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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/180,269 07/08/99 BALL

K CCI-007US

EXAMINER

HM12/0308

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BOSTON MA 02109

MURPHY, T

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

03/08/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/180,269

Applicant(s)

BALL ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-12, 17 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7, 9 and 31-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 6, 8, 10-12 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Sequence Comparison A*.

### **DETAILED ACTION**

Claims 1, 13-16 and 18-30 were cancelled, and claims 2-4, 6, 8, 10, 17, 31-33, 35-36 and 38-39 were amended, in Paper No. 10, 12/20/2000.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-17 in Paper No. 10, 1/3/2001 is acknowledged. Applicant's submission of the instant application as a 371 is acknowledged, however the first claim does not provide a technical feature that is distinguished over the prior art, as evidenced by WO 94/09135, which discloses that inhibitors of p21 can be introduced into cells and interfere with p21 binding to complex members (i.e. including cyclin D) Therefore, the instant invention lacks Unity of Invention and restriction is set forth as it applies to U.S. practice

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-5, 7, 9 and 31-41 are withdrawn from further consideration as being drawn to a non-elected invention, pursuant to 37 CFR 1.142(b). Claims 2, 6, 8, 10-12 and 17 are under consideration.

### ***Claim Objections***

According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Sequences appear in claim 9 of the specification but are not identified by SEQ ID NO as required.

Appropriate correction is required.

Claim 2 is directed to non-elected subject matter. Appropriate correction is required.

***Claim Rejections - 35 USC § 112 second paragraph***

Claims 2, 6, 8, 10-12 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 17 are vague and indefinite in the recitation of the term "and/or" because it is unclear if Cdk 4 is necessary for the practice of the claimed method. Claims 6, 8 and 10-12 are vague and indefinite insofar as they depend on the recitation in claim 2 of the term "and/or".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims , 2, 6, 8, 10-12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/09135 (Beach et al.) in view of Xiong et al. (1993).

Beach et al. discloses the association between cyclin D, p21 and cdk 4, and its disruption upon introduction of SV40 tumor virus or its gene product (page 3, lines 35-36). Beach et al.

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discloses that inhibitors of p21 can be introduced into cells and interfere with p21 binding to complex members (i.e. including cyclin D) (page 4, line 27-28). Beach et al. also discloses that drugs which alter p21 function can be used to inhibit or enhance cell division (page 25, lines 22-23). Beach discloses a method of screening compounds for their ability to inhibit or suppress the transformation of a cell, which may include prevention of formation of complexes including cyclin D, p21 and CDK (page 24, line 12 to page 25, line 9). Beach et al. does not list the sequence of p21, hence the Xiong et al. reference is cited to exemplify that the sequence of p21 comprises the claimed KRRLIFSK sequence (see Sequence Comparison A, attached).

Therefore, it would have been obvious to one of skill in the art at the time the invention was made to practice the method disclosed in Beach et al. to screen for a compound which modulates the interaction of p21 and cyclin D and cdk 4. The motivation is provided in Beach et al. which discloses that p21 is known to associate with cyclin kinases only in normal, untransformed cells, and thus offers specificity in modulating cell division, for example the ability to selectively alter cell division in particular cell types or at a particular point in the cell cycle (page 4, lines 7-15).

### ***Conclusion***

No claim is allowed.

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
March 7, 2001

*Prema Mertz*  
**PREMA MERTZ**  
**PRIMARY EXAMINER**

## Sequence Comparison A

RESULT 1

S39358

cyclin kinase inhibitor - human (fragments)

C;Species: Homo sapiens (man)

C;Date: 25-Feb-1994 #sequence\_revision 17-Nov-1995 #text\_change 17-Mar-1999

C;Accession: S39358

R;Xiong, Y.; Hannon, G.J.; Zhang, H.; Casso, D.; Kobayashi, R.; Beach, D.

Nature 366, 701-704, 1993

A;Title: p21 is a universal inhibitor of cyclin kinases.

A;Reference number: S39357; MUID:94081955

A;Accession: S39358

A;Status: preliminary

A;Molecule type: protein

A;Residues: 1-47 <XIO>

Query Match 100.0%; Score 38; DB 2; Length 47;  
Best Local Similarity 100.0%; Pred. No. 0.062;  
Matches 8; Conservative 0; Mismatches 0; Indels 0;  
Gaps 0;

Qy 1 KRRLIFSK 8  
| | | | | | | |  
Db 40 KRRLIFSK 47